4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2022-D-0080]

Formal Meetings Between the Food and Drug Administration and Sponsors or Requestors of Over-the-Counter Monograph Drugs; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled "Formal Meetings Between FDA and Sponsors or Requestors of Over-the-Counter Monograph Drugs." This draft guidance provides recommendations to industry on formal meetings between FDA and sponsors or requestors of over-the-counter (OTC) monograph drugs.

DATES: Submit either electronic or written comments on the draft guidance by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*] to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: https://www.regulations.gov. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to https://www.regulations.gov will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or

confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on https://www.regulations.gov.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2022-D-0080 for "Formal Meetings Between FDA and Sponsors or Requestors of Over-the-Counter Monograph Drugs." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at https://www.regulations.gov or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy,

including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on https://www.regulations.gov. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to https://www.regulations.gov and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the SUPPLEMENTARY INFORMATION section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Trang Tran, Center for Drug Evaluation and Research (HFD-600), Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 240-402-7945.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled "Formal Meetings Between FDA and Sponsors or Requestors of Over-the-Counter Monograph Drugs." This draft guidance provides recommendations to industry on formal meetings between FDA and sponsors or requestors of nonprescription drugs without approved new drug applications that are governed by section 505G of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355h) (hereafter referred to as *OTC monograph drugs*).

Section 505G of the FD&C Act was added by the Coronavirus Aid, Relief, and Economic Security Act (CARES Act) (Pub. L. 116-136), which was enacted on March 27, 2020. As required by section 505G(l) of the FD&C Act, this draft guidance, when finalized, will discuss the procedures and principles for formal meetings between FDA and sponsors or requestors for an OTC monograph drug (hereafter referred to collectively as *meeting requesters*). In doing so, and as required by section 505G(h) of the FD&C Act, this draft guidance, when finalized, will describe procedures under which meeting requesters can meet with appropriate FDA officials to obtain recommendations on the studies and other information necessary to support submissions under section 505G of the FD&C Act, to obtain information on other matters relevant to the regulation of nonprescription drugs, and to obtain recommendations on the development of new OTC monograph drugs. As required by section 505G(i) of the FD&C Act, this draft guidance, when finalized, will also describe procedures to facilitate efficient participation in joint meetings by multiple meeting requestors and/or organizations nominated by them to represent their interests.

This draft guidance does not apply to meetings for the development of nonprescription drug products intended for submission in new drug applications or abbreviated new drug applications under section 505 of the FD&C Act. This draft guidance does not apply to meetings between FDA and pre-investigational new drug or investigational new drug sponsors. For the

purposes of this draft guidance, a *formal meeting* includes any meeting that is requested by a meeting requester following the procedures provided in this draft guidance and includes meetings conducted in any format (i.e., face to face, teleconference/videoconference, or written response only).

In support of the CARES Act, FDA agreed to specific performance goals and procedures described in the document "Over-the-Counter Monograph User Fee Program Performance Goals and Procedures--Fiscal Years 2018-2022," commonly referred to as the OMUFA Commitment Letter (the document can be accessed at https://www.fda.gov/media/106407/download and the document with updated goal dates for fiscal years 2021-2025 can be accessed at https://www.fda.gov/media/146283/download). The OMUFA Commitment Letter includes meeting management goals for formal meetings that occur between FDA and meeting requesters. In the OMUFA Commitment Letter, FDA committed to issuing this draft guidance under specific timelines.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on "Formal Meetings Between FDA and Sponsors or Requestors of Over-the-Counter Monograph Drugs; Draft Guidance for Industry." It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

Under section 505G(o) of the FD&C Act, the Paperwork Reduction Act of 1995 does not apply to collections of information made under section 505G of the FD&C Act. The information collections made in this guidance implement the provisions of three subsections of section 505G: (1) section 505G(l)(1), which requires FDA to issue guidance that specifies the procedures and principles for formal meetings between FDA and sponsors or requestors for drugs subject to section 505G; (2) section 505G(h), which requires FDA to establish procedures under which

meeting requestors can meet with appropriate FDA officials to obtain advice on the studies and other information necessary to support submissions under section 505G, other matters relevant to the regulation of nonprescription drugs, and the development of new nonprescription drugs under section 505G; and (3) section 505G(i), which requires FDA to, among other things, establish procedures to facilitate efficient participation in joint meetings by multiple meeting requesters and/or organizations nominated by them to represent their interests. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required for these collections of information.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at either https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, https://www.fda.gov/regulatory-information/search-fda-guidance-documents, or https://www.regulations.gov.

Dated: February 1, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

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